REMARKS

I. Status Summary

Claims 1-4, 7-10, and 58-71 are pending in the subject U.S. patent application and have been examined by the United States Patent and Trademark Office (hereinafter "the Patent Office") in a non-final Official Action dated June 10, 2010 (hereinafter the "Official Action"). Claims 61-68 have been withdrawn as being directed to non-elected subject matter. Claims 1-4, 7-10, and 58-71 presently stand rejected.

The Patent Office has withdrawn the enablement rejection of claims 58-60 and some of the enablement rejections of claims 1 and 7 in view of Applicants' arguments in the previous Amendment.

The restriction of claims 61-68 has been maintained upon the contention that the claims are directed to non-elected subject matter. Specifically the Patent Office alleges that claims 61-68 are directed to administering two antigens whereas applicants have made a species election of administering DAZL. The Patent Office also maintains that claims 63-68 are drawn to producing a chimeric avian relevant to invention Groups III and IV of the Restriction Requirement sent May 16, 2007, but not Applicants' elected Group II. The Patent Office now contends that new claims 69-71 also encompass administering two antigens and that they would thus be examined as they relate to administering the elected antigen species, DAZL.

The Patent Office has rejected claims 1-4, 7-10, 58-60, and 69-71 under 35 U.S.C. § 112, first paragraph, for allegedly introducing new matter. The Patent Office contends that the phrase "antigen associated with primordial cell development" is not described in the specification such that one having ordinary skill in the art would know the inventors had possession of the invention at the time the application was filed. The Patent Office has rejected claims 69-70 upon the contention that "an amount of antigen associated with primordial germ cells sufficient to generate... " and the range "50-200 µg" are also unsupported by the specification.

The Patent Office has maintained a rejection to claims 1-4 and 7-10 and has further rejected claims 69-71 under the enablement provision of 35 U.S.C. § 112, first paragraph, upon a contention with respect to the phrase "any antigens associated with

PGC development" that merely restates the Patent Office's contention upon which the same rejection was made in previous Official Actions.

The Patent Office has maintained a rejection to claims 1-4, 7-10, and 58-60 and has further rejected claims 69-71 under 35 U.S.C. § 112, second paragraph, upon the contention that the following phrase is indefinite:

> "*[S]ufficiently high concentration of antibodies that bind to the antigen expressed by an avian embryo present within the egg to thereby decrease endogenous PGC numbers [or development] in the avian embryo are decreased [inhibited].*"

See Official Action, page 8. Claim 69 has been rejected by the Patent Office for being indefinite because it allegedly lacked an antecedent basis for the phrase "the female bird." The Patent Office also contends the term "the antigen" in claim 69 lacks an antecedent basis because the preceding phrase "an amount of antigen" could include more than one antigen.

Reconsideration of the application as amended and in view of the remarks presented herein below is respectfully requested.

II. Discussion of Withdrawn Claims and Objections to the Claims

The restriction of claims 61-68 has been maintained upon the contention that the claims are directed to non-elected subject matter. Particularly, the Patent Office alleges that claims 61-68 are directed to administering two antigens whereas applicants have made a species election of administering DAZL. The Patent Office also maintains that claims 63-68 are drawn to producing a chimeric avian relevant to invention Groups III and IV of the Restriction Requirement sent May 16, 2007, but not Applicants' elected Group II. The Patent Office now contends that new claims 69-71 also encompass administering two antigens and that they would thus be examined as they relate to administering the elected antigen species, DAZL.

It is respectfully requested that the cancellation of claims 61-71 be held in abeyance until such time as a generic claim might be in the condition for allowance

such that possible consideration of the additional species of antigens or combinations of antigens might be considered. For example, it is believed that present claims 1, 7, 58 and 69 are representative generic claims. See also the Restriction/Election Requirement dated May 16, 2007, wherein the Patent Office appears to take the position that all claims are generic. It is further respectfully requested that the search be extended to additional species at this time since it appears to be indicated at page 10 of the Official Action that no art has been found with respect to the species election DAZL.

It is noted that the Examiner has presented a claim objection at page 2 of the Official Action which reads as follows:

> Consider: -i) immunizing a female bird with DAZL, ii) obtaining an egg comprising an embryo from the female bird, wherein the egg comprises antibodies that recognize DAZL in an amount sufficient to bind to DAZL on PGCs of the embryo and decrease the number of PGCs in the embryo, iii) repopulating the gonad of the embryo with donor PGCs of a different strain of the same species, and iv) obtaining a chimeric avian from the embryo.-- Please point to support for each step in the specification originally filed upon amendment.

Page 2, Official Action.

It is believed that the Examiner is suggesting adding a claim based on the paragraph presented above. In lieu of this suggestion, applications respectfully submit the above-noted amendments and the arguments below. The Examiner is invited to contact the undersigned by telephone to discuss this point.

III. Response to the New Matter Objection

The Patent Office rejected to claims 1-4, 7-10, 58-60, and 69-71 under 35 U.S.C. § 112, first paragraph, for allegedly introducing new matter. The Patent Office contends that the phrase "antigen associated with primordial cell development" is not described in the specification such that one having ordinary skill in the art would know the inventors had possession of the invention at the time the application was filed. The Patent Office also rejected claims 69-70 upon the contention that "an amount of antigen associated with primordial germ cells sufficient to generate... " and the range "50-200 μg" are also unsupported by the specification. These rejections are respectfully traversed.

Initially, it is noted that the Official Action asserts that the phrase "antigen associated with primordial cell development" is not described in the specification. It is respectfully submitted that this phrase does not appear in claims 1-4, 7-10, 58-60, and 69-71. Rather, the phrase "antigen associated with primordial germ cell development" appears in these claims either directly or by virtue of dependency from a base claim. Thus, it is believed that the instant rejection might pertain to this phrase, which includes the recitation "primordial germ cell" instead of "primordial cell". Applicants proceed with the following remarks based on this assumption.

Support for the phrase at issue can be found throughout the subject U.S. patent application as filed, expressly and/or inherently. This is believed to be the appropriate standard for support for amendments.

To elaborate, support for the above-mention phrase can be found at page 1 of the subject U.S. patent application as filed, lines 10-14, which recite "[m]ore particularly, the presently disclosed subject matter relates to the use of antibodies that bind to antigens associated with primordial germ cells to modulate the development of primordial germ cells during embryogenesis in avians." This phrase is believed to clearly support that the antigens can be associated with primordial germ cell development, as recited in the present claims, since the antigens can be associated with the modulation of the development of primordial germ cells.

Further support can be found in the paragraph at page 11, line 27 through page 12, line 17, of the subject U.S. patent application as filed. This paragraph reads as follows:

> The antibodies of the presently disclosed subject matter bind to an antigen associated with primordial germ cells. As used herein, the term "associated with primordial germ cells" refers to a antigens comprising an epitope that is either expressed by, or post-translationally attached to, a polypeptide expressed by a primordial germ cell (for example, a cell surface marker) or by a cell capable of influencing the migration and/or development of a primordial germ cell (for example, migration factors, growth factors, and polypeptides expressed by cells present in the microenvironment in which PGCs are present or develop). Such antigens include, but are not limited to epitopes present on an SSAE-1, ovomucin-like protein (OLP), Steel Factor (c-kit ligand), germ cell-less, dead end, VASA (including, but not limited to the chicken VASA homolog, CVH),

> DAZL, nanos, stella, and fragilis polypeptides, and the antigens recognized by the antibodies EMA-1, QH-1, FC10.2, S-FC10.2, NC-1, 2C9, QCR1, AGC5, AGC7, and AGC13. *Reviewed in* Tajima, *Avian Poultry Biol Rev* 13:15-20, 2002. *See also* Buehr, *Exp Cell Res* 232, 194-207, 1997; D'Costa & Petitte, *Intl J Devel Biol* 43:349-56, 1999; Urven *et al.*, *Development* 103:299-304, 1988; Hay *et al.*, *Cell* 55:577-587, 1988; Lasko & Ashburner, *Nature* 335:611-617, 1988; Raz, *Nature Genetics* 4:690-700, 2003; Houston & King, *Development* 127:447-56, 2000; Cooke *et al.*, *Hum Mol Genet* 5:513-516, 1996; Kimura *et al.*, *Biochem Biophys Res Commun* 262:223-30, 1999; Weidinger *et al.*, *Curr* Biol 13:1429-34, 2003; and references therein.

This portion of the specification is believed to clearly demonstrate that the antigen can comprise an epitope and is either expressed by or post-translationally attached to a cell capable of influencing the development of a primordial germ cell. Thus, this section is believed to clearly supports the recitation in the claim "an antigen associated with primordial germ cell development." Accordingly, withdrawal of the instant rejection is respectfully requested.

Further, at page 13, lines 10 through 15 of the subject U.S. patent application as filed, the role of the VASA polypeptide in germ cell development, including whole PGC development, is described. The VASA polypeptide is an example of an antigen associated with primordial germ cell development. See also the section of the specification from page 11, line 27 through page 17 presented hereinabove. Additionally, at page 25, lines 13 through 23 of the subject U.S. patent application as filed, it is noted that the disclosed peptide antigens disclosed as VASA-n, VASA-c, DAZL-n and DAZL-c are intended to be representative only and other antigenic peptides and polypeptides, including the full length version of a polypeptide associated with PGC development can be used as immunogens. These sections are also believed to provide appropriate support for the instant claim language. See also page 30, line 20 through page 31, line 1. Summarily, it is believed that the phrase at issue is supported throughout the subject U.S. patent application as filed and withdrawal of the instant rejection is respectfully requested.

The Patent Office has also rejected new claims 69-70 under 35 U.S.C. § 112, first paragraph, for allegedly introducing new matter upon the contention that the phrase

"an amount of antigen associated with primordial germ cells sufficient to generate" and the range "50 to 200 nanograms" are unsupported by the specification."

Applicants respectfully disagree. The phrase in claim 69 is believed to find support at least in the same locations as discussed hereinabove with respect to the phrase "antigen associated with primordial germ cell development". Additional support can be found at page 25, lines 1-11, which read as follows:

> Avians, in particular chickens, have become an increasingly common source of large-scale production of polyclonal antibodies due to the fact that large amounts of antibodies are transferred from serum to the yolk of eggs during egg production. *See* Rose *et al.*, *Eur J Immunol* 4:521, 1974. The presently disclosed subject matter takes advantage of this phenomenon to effect PGC development in embryos by immunizing female avians with antigens associated with PGCs, which collect in the yolk. These antibodies can then bind to their cognate antigens during avian embryogenesis, thereby affecting the biological activities of polypeptides associated with PGC development.

Emphasis added. Additional support can be found in claims 1 and 7 as filed, which each recited: "immunizing a female bird with an antigen associated with primordial germ cells, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies specific for the antigen to modulate numbers of endogenous PGCs in an avian embryo present within in the egg."

Additional support for the noted phrase and for the range "50-200 micrograms" can be found in Example 1, at page 52, lines 8-16, of the subject U.S. patent application as filed, among other places. This section is presented as follows:

> Sexually mature Leghorn females were immunized intramuscularly with 100-200 μg of a single conjugated peptide or combination of peptides (pectoralis major). Blood samples were taken after immunization, allowed to clot over night at 4°C, and the resulting serum samples were stored at -20°C for subsequent antibody determination. A secondary immunization (50-100 μg of conjugated peptide + TMA) was administered 14 days later. Blood samples were also obtained three days following the second challenge from both immunized hens and non-injected controls. The resulting serum samples were stored at -20°C for subsequent antibody determination.

It is noted that two immunizations were performed, one in the range of 100-200 micrograms of single conjugated peptide and the second immunization in the range 50-100 micrograms of conjugated peptide + TMA. Thus, support for the amount of antigen and for the amount of antigen at both ends of the range 50 and 200 micrograms can be found in this Example.

Additional support can be found in Example 2, at page 56, lines 3-17, of the subject U.S. patent application as filed. This Example reports the results of the immunization of Example1, for example as follows:

> Reduction of PGCs was determined by counting immunohistochemically stained PGCs in 10 sections of both left and right gonads of each embryo. The 10 sections were selected from the mid-region of the gonads. At least three sections were skipped between any two selected sections to avoid counting individual PGCs more than once. The results of this analysis are presented in Figure 4. As shown in Figure 4, each of the peptide antigens Vasa-N, Vasa-C, Dazl-N, and Dazl-C were able to induce an immune response in chickens, which resulted in the deposition of anti-antigen antibodies in the yolk of eggs produced by the immunized females. The presence of the antibodies in the eggs reduced PGCs numbers in developing stage 27 embryos. Immunizing females with individual peptides resulted in an approximately 35-55% reduction in endogenous PGC numbers, while immunization with two or more peptides simultaneously resulted in an approximately 55-70% reduction in endogenous PGCs.

Emphasis added.

Accordingly, it is believed that the instant of claims 1-4, 7-10 and 58-71 under 35 U.S.C. § 112, first paragraph for allegedly introducing new matter has addressed. Withdrawal of this rejection is respectfully requested. Allowance of the noted claims is also respectfully requested.

V. Response to the Enablement Rejection

The Patent Office maintained a rejection of claims 1-4 and 7-10 and further rejected claims 69-71 under the enablement provision of 35 U.S.C. § 112, first paragraph, upon the contention that the phrase. This rejection is respectfully traversed.

It appears that the primary basis of this rejection is that the present specification fails to adequately teach how to use the method claimed with any antigen "associated with PGCs". However, the instant specification provides a definition for the term "associated with primordial germ cells". See page 11, line 27 through page 12, line 17, of the subject U.S. patent application as filed, reproduced hereinabove.

Furthermore, applicants submit that the specification as filed discloses a series of exemplary antigens associated with primordial germs cells, which include, but are not limited to SSAE-1, ovomucin-like protein (OLP), Steel Factor (c-kit ligand), germ cell-less, dead end, VASA (including, but not limited to the chicken VASA homolog, CVH), DAZL, nanos, stella, and fragilis polypeptides (*see* specification at page 11, line 27 to page 12, line 9). Given that the instant claims must be viewed from the perspective of one of ordinary skill in the art after review of the instant specification, applicants respectfully submit that one of ordinary skill in the art would also understand without undue experimentation which antigens would represent appropriate antigens for use in the instantly claimed methods.

Therefore, even assuming *arguendo* that certain antigens might be undesirable for use in the instant methods, applicants respectfully submit that one of ordinary skill in the art would understand which antigens would in fact be expected to be useful in the instant claims, the Patent Office has not presented a *prima facie* case of lack of enablement based on the fact that certain embodiments that fall within the scope of the claim might be inoperative. This is set forth in M.P.E.P. § 2164.08(b), which states in part:

> The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984)

Since applicants respectfully submit that with respect to antigens associated with PGC development, one of ordinary skill in the art "could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with

expenditure of no more effort than is normally required in the art", the Patent Office's present assertions do not support the instant rejection. Further, one of ordinary skill in the art after review of the instant specification, applicants respectfully submit that one of ordinary skill in the art could practice the instantly claimed methods without undue experimentation.

Moreover, representative examples are provided in the subject U.S. patent application as to how to reduce PGCs in an avian embryo as provided in present claims 1, 7, and 69. See Examples 1-5, and the representative portions of Examples 1 and 2 set forth herein above. Accordingly, withdrawal of the instant rejection is respectfully requested.

Summarily, the Patent Office has employed an improper analysis in assessing the compliance of instant claims 1, 7, and 69 with the enablement requirement of 35 U.S.C. § 112, first paragraph. None of the assertions presented in the Final Official Action establishes a *prima facie* case of non-enablement of claims 1, 7, or 69 and thus applicants respectfully request that the instant rejection be withdrawn at this time. Applicants further respectfully submit that claims 2-4, 8-10, 70, and 71 all depend from one of claims 1, 7, or 58 and thus it is also believed that a *prima facie* case of non-enablement of these claims has not been presented. Allowance of claims 1, 7 and 69 and their dependent claims is also respectfully requested.

Additionally, it is noted that claim 71 particularly recites that the antigen is DAZL. Without acquiescing to the contentions of the Patent Office, Claim 71 has also been amended to recite: "wherein the egg comprises antibodies that recognize DAZL in an amount sufficient to bind to DAZL on primordial germ cells of the embryo and decrease the number of primordial germ cells in the embryo." Support for this amendment can be found throughout the subject U.S. patent application as filed, including at Example 2, at page 56, lines 3-17, of the subject U.S. patent application as filed, reproduced herein above. For at least these additional bases, claim 71 is believed to be in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph. Allowance of claim 71 is also respectfully requested.

V. Response to the Indefiniteness Rejections

The Patent Office maintained the rejection of claims 1-4, 7-10, and 58-60 and further rejected claims 69-71 under 35 U.S.C. § 112, second paragraph, upon the contention that the following phrase is indefinite:

> "*[S]ufficiently high concentration of antibodies that bind to the antigen expressed by an avian embryo present within the egg to thereby decrease endogenous PGC numbers [or development] in the avian embryo are decreased [inhibited].*"

See Official Action, page 8. Claim 69 was rejected by the Patent Office for being indefinite because it allegedly lacked an antecedent basis for the phrase "the female bird." The Patent Office also contends the term "the antigen" in claim 69 lacks an antecedent basis upon the further contention that the preceding phrase "an amount of antigen" could include more than one antigen.

This rejection is respectfully traversed. It is respectfully submitted that 35 U.S.C. § 112, second paragraph requires no more than that one of ordinary skill in the art can understand the claim language upon review of the specification of a given U.S. patent application. It is respectfully submitted this standard has been met in view of the extensive guidance provided by the subject U.S. patent application.

The Patent Office contends that the specification does not teach how to determine whether PGC numbers decrease without sacrificing the avian, that the concentration of antibodies required to decrease the number or development of PGCs and maintain a viable embryo is not set forth in the specification or the art at the time of filing, and that the specification does not provide an assay for those of skill to determine when the amounts of antibodies were "sufficiently high" enough to decrease PGC numbers in an embryo that becomes a viable avian.

Applicants respectfully submit that these assertions are inaccurate and also do not support the instant rejection.

To elaborate, the Patent Office first contends that the specification does not teach how to determine whether PGC numbers decrease without sacrificing the avian.

Applicants respectfully disagree and submit that this assertion also fails to support the instant rejection for at least the following reasons.

First, the experiments that are explicitly disclosed in the specification indicate that immunizing female avians with antigens associated with PGCs resulted in at least a 35% reduction in PGC numbers in the embryos. This was indeed determined by sacrificing the embryos, but applicants respectfully submit that once it is shown that immunizing the female avians predictably resulted in decreased PGC numbers, one having skill in the art would have no need to test each and every embryo for a similar result. The Patent Office has identified no basis for its assertion that the decrease in PCG numbers observed in the embryos disclosed in Example 2 of the instant specification would not also occur in other embryos that experienced the same treatment, such as those used in Example 3 (Specification, page 57, lines 8-9) to repopulate the PGC-depleted embryos with donor cells, or in Examples 4 (*Id.*, page 59, lines 5-6), and 5 (*Id.*, page 60, line 10) to produce avian chimeras.

Example 5 describes that embryos are treated to deplete PGCs, using the protocols described in the earlier examples. These same embryos then receive donor PGC's, are allowed to hatch and are used in breeding. Pigment markers observed in the offspring of the treated (PGC-depleted) birds but not observed in the offspring of the untreated (control) birds indicate transmission of gametes derived from the donor PGC's. One of ordinary skill in the art understands that obtaining a higher percentage of pigmented chicks in the offspring population demonstrates that sufficient antigen was administered and a sufficient amount of antibodies inhibited or decreased the endogenous PGCs in the recipient embryo. This is determined without sacrificing the embryos. Using Example 5 as an illustration, if there were none or fewer pigmented chicks produced then it is clear to one having skill in the art that there were more endogenous PGCs in the treated embryos.

Continuing, applicants submit there is no requirement that the determination of a decrease in PGC number itself be performed on every single treated embryo or that it be performed exclusively *in ovo*. Rather, the techniques disclosed for visualizing PGC numbers *in ovo* can be employed on a subset of treated animals, and the results of the

tests performed on these avians can be extrapolated with a high degree of predictability to similar treated avians that are permitted to hatch.

Applicants further direct the Patent Office's attention to Example 2 for evidence that the claimed treatments predictably reduce PGCs as set forth in the following sections from page 56:

> Immunizing females with individual peptides resulted in an approximately 35-55% reduction in endogenous PGC numbers, while immunization with two or more peptides simultaneously resulted in an approximately 55-70% reduction in endogenous PGCs.
>
> Statistical analysis. Treatment differences for the average number of PGCs/embryo were analyzed using the GLM procedure of the SAS System (SAS Institute Inc., Cary, North Carolina, United States of America). The model was PGC = treatment hen. Treatment differences were significant at $p < .0002$.

Emphasis added. Applicants respectfully submit that a demonstration of highly significant differences between treated and untreated avians ($p < 0.0002$ would be understood by one of ordinary skill in the art to be very highly significant) would show one of ordinary skill in the art that that treatment predictably reduces PGC numbers. Thus, contrary to the Patent Office's assertion, the instant specification does indeed inform one of ordinary skill in the art that "[t]he ability to predict whether PGC numbers had decreased after immunizing an avian with an antigen" was predictable.

The Patent Office contends that the instant specification does not teach the means to assess the amount of antibodies without sacrificing the embryo. This contention is refuted at least with the following remarks.

The methods of claims 1, 7, 58, and 69 can be used to generate PGC-depleted embryos that can be employed as a starting point for creating different types of chimeric avians. As is explained in Example 3, page 57, line 12, of the instant Specification, the eggs containing PGC-depleted embryos (produced by the methods of claims 1, 7, 58, and 69) can be repopulated with donor PGCs at developmental stage 14-17 of the Hamburger & Hamilton staging system. One having skill in the art knows that this time frame corresponds to about 50-64 hours after the egg was laid. Such PGC-depleted embryos can be sold and shipped during this at least four day period to a user who can

use the product of the methods as he/she sees fit including to repopulate the embryo with proprietary transgenic PGCs (Specification, page 37, lines 20-22) or with PGCs from any number of different endangered species (Specification, page 14, lines 7-9). Thus, applicants respectfully submit that the claimed methods clearly do have an enabled use (*i.e.*, the production of a PGC-depleted avian embryo) and that the products of the methods are useful in and of themselves.

Additionally, applicants respectfully submit that after review of the instant specification, one of ordinary skill in the art would understand that a degree of germline chimerism (*i.e.*, the contribution of the donor PGCs to the recipient gonad) would be easily assayable by analyzing chimeric animals and/or by breeding the chimeras once they attain sexual maturity (as was demonstrated in Example 5). Applicants respectfully submit that standard molecular biology techniques can be employed for assaying germline chimerism, and these assays can be performed on either interspecific chimeras or intraspecific chimeras.

To elaborate, routine techniques can be employed for isolating the terminal differentiated products of PGC differentiation (*i.e.*, the eggs and sperm of chimeric avians). With respect to both interspecific and intraspecific chimeras, routine genetic analysis can be employed to quantitate an extent of germline chimerism. Stated another way, easily assayable genetic differences exist between species and among different members of the same species, and these can be exploited to assay germline chimerism that would be within the skill of one of ordinary skill in the art upon a review of the instant disclosure.

In view of the remarks above, and as demonstrated in Example 5 of the specification, applicants respectfully submit that one of ordinary skill in the art would understand after review of the instant specification that standard breeding techniques could be employed to assay for germline chimerism. The techniques that would be required for assaying germline chimerism by breeding chimeras are all routine in the field of animal husbandry, and since one of the consequences of reducing endogenous PGCs is that germline chimerism is enhanced (*see* the instant specification at page 1, line 31 to page 2, line 1), applicants respectfully submit that routine breeding

experiments can be employed to confirm the effect of the immunizations if for some reason it were necessary.

The specification as filed indicates on page 1, line 31 to page 2, line 1, that chimerism can be increased by depleting endogenous PGCs. Routine comparisons can be employed to ensure that the treated embryos had reduced PGC numbers. Further, applicants respectfully submit that whether or not the specification *per se* teaches how to do this, one of ordinary skill in the art would know several methods for accomplishing this goal upon a review of the instant specification. Therefore, one of ordinary skill in the art would easily be able to identify when a sufficiently high concentration of antibodies specific for the antigen to decrease the PGC numbers or development in an avian embryo had occurred based on the guidance provided in the instant specification.

Next, the Patent Office asserts that the concentration of antibodies required to decrease the number or development of PGCs and maintain a viable embryo is not set forth in the specification or the art at the time of filing. This apparent requirement that a specific concentration be recited in the specification is believed to be clearly improper. Rather, applicants respectfully submit that all that is necessary is that one of ordinary skill in the art understand how to practice the methods of claims 1, 7, 58, and 69, and understand when the methods of claims 1, 7, 58, and 69 have been successfully executed. Given that all of the techniques required to assess the successful completion of the methods would be apparent to one of ordinary skill in the art based on the guidance provided in the instant specification, the instant assertion fails to support a rejection under 35 U.S.C. § 112, second paragraph.

The Patent Office asserts that the specification does not provide an assay for those of skill to determine when the amounts of antibodies were "sufficiently high" enough to decrease PGC numbers in an embryo that becomes a viable avian. Applicants respectfully submit that they have provided ample guidance in the instant specification as filed such that one of ordinary skill in the art would in fact have known how to assess PGC decreases in an avian that had hatched, (*e.g.* via breeding techniques) and thus for this additional reason, the instant assertion fails to support a rejection under 35 U.S.C. § 112, second paragraph.

Applicants respectfully submit that the phrase at issue is functional language that is perfectly acceptable under M.P.E.P. § 2173.01, which states in part:

> Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

Claim 69 was also rejected by the Patent Office for being indefinite because it allegedly lacked an antecedent basis for the phrase "the female bird." Applicants respectfully disagree because the phrase "a female bird" precedes this phrase in claim 69. Withdrawal of this rejection is respectfully requested. Allowance of claim 69 is also respectfully requested.

The Patent Office also contends the term "the antigen" lacks an antecedent basis upon the further contention that the preceding phrase "an amount of antigen" could include more than one antigen. Without acquiescing to the contentions of the Patent Office and to expedite prosecution, applicants hereby amend the claim to recite applicants' understanding of the Patent Office's suggested language, "an amount of an antigen." Withdrawal of this rejection is respectfully requested. Allowance of claim 69 is also respectfully requested.

Thus, the Patent Office has not presented a *prima facie* case of lack of compliance with 35 U.S.C. § 112, second paragraph, of claims 1, 7, 58, and 69. Applicants further respectfully submit that claims 2-4, 8-10, 59-60, and 69-71 all depend from one of claims 1, 7, or 58, and thus it is also believed that the instant rejection is inapplicable to these claims as well. As a result, applicants respectfully request that the instant rejection be withdrawn at this time. As a result, applicants respectfully submit that claims 1-4, 7-10, 58-60, and 69-71 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

Additionally, it is noted that claim 71 particularly recites that the antigen is DAZL. Without acquiescing to the contentions of the Patent Office, Claim 71 has also been amended to recite: "wherein the egg comprises antibodies that recognize DAZL in an

amount sufficient to bind to DAZL on primordial germ cells of the embryo and decrease the number of primordial germ cells in the embryo." Support for this amendment can be found throughout the subject U.S. patent application as filed, including at Example 2, at page 56, lines 3-17, of the subject U.S. patent application as filed, reproduced herein above. For at least these additional bases, claim 71 is believed to be in compliance with 35 U.S.C. § 112, second paragraph. Allowance of claim 71 is also respectfully requested.

CONCLUSIONS

Should there be any minor issues outstanding in this matter, the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any deficiencies or credit any overpayment in fees associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,
JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date: 12/10/2010

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